K033018

MAY - 5 2004

510(k) Summary of Safety and Effectiveness

Submitter Information:

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CE Consultancy, Inc.
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Device Name:

Trade Name: Stimulong Plus Catheter Sets
Common Name: Anesthesia Conduction Kit
Classification Name: Anesthesia Conduction Kit (Reference, 21CFR, 868.5140, April 1, 2003)

Predicate Devices:

The Stimulong Plus Catheter sets consist of a Pajunk Unipolar conduction needle with either a facet tip, a Sprotte tip, or a Tuohy tip, all with nerve stimulus connector, tubing, a conduction catheter and catheter adapter. All Pajunk conduction cannula with nerve stimulus connector and tubing have been cleared for market by the FDA under 510(k) number K000722 (Unipolar facet and Sprotte tip). The Plexolong anesthesia sets which include a catheter and catheter adapter were cleared for market under FDA 510(k) No. K013041 and the Tuohy tip cannula with stimulus connector and tubing, catheter and catheter adapter have been cleared for market by the FDA under 510(k) No. K023218, (Plexolong Tuohy tip conduction anesthesia sets). The indications for use for all Plexolong sets is identical to that for the proposed Stimulong Plus Catheter sets, i.e. to gain entry and inject local anesthetics and to induce regional anesthesia and enable continuous delivery for up to 72 hours. The Arrow International StimuCath™ continuous nerve block set cleared for market by the FDA under 510(k) No. 030937 includes a conduction catheter for the identical intended use.

The contract sterilizer and sterilizing process are the same as those used for the Pajunk Plexolong sets. The packaging materials are also the same as those used to package the Pajunk Plexolong sets.

Device Description:

The Pajunk Stimulong Plus Catheter Sets are single use, sterile, non-pyrogenic and latex free conduction anesthesia sets intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. The Stimulong Plus Catheter sets consist of a single use sterile, non-pyrogenic conduction needle with tubing, a conduction catheter and catheter adapter. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction catheter to its tip via the catheter adapter.

Intended Use:

The Pajunk Stimulong Plus Catheter Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction catheter to its tip via the catheter adapter.

Technology Characteristics:

The Pajunk conduction needles, which include the physical dimensions, coating, connector, tubing, metal and plastics, have been cleared under 510(k) numbers K000722, K013041 and K023218. The material used to manufacture the Pajunk catheter and catheter adapter except for the conductive catheter tip and wire are identical to the materials used to manufacture the catheter and catheter adapter of the predicate devices described earlier in this *510(k) Summary of Safety and Effectiveness.* Biocompatibility testing of the conductive tip, wire and alternate plastic material is located in *Section 7* of this submission. Use of a conduction catheter was cleared by FDA under 510(k) No. K030937. The Stimulong Plus Catheter Sets are supplied in polypropylene containers that are sealed to assure sterility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Pajunk GmbH
c/o Mr. Burk A. Brandt
CE Consultancy, Incorporated
5010 NW Crescent Valley Drive
Corvallis, OR 97330

Re: K033018
Trade/Device Name: Pajunk Stimulong Plus Catheter Set
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II
Product Code: CAZ
Dated: March 9, 2004
Received: March 11, 2004

Dear Mr. Brandt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-5613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K033018

Device Name: Pajunk Stimulong Plus Catheter Sets

Indications for use:

The Pajunk Stimulong Plus Catheter Sets are intended for delivery of continuous conduction anesthesia of peripheral nerves and plexus for up to 72 hours. Continuous delivery is accomplished using the conduction catheter. To assist the physician pinpoint the area of application an electrical stimulus can be applied to the conduction needle and after placement of the conduction catheter to its tip via the catheter adapter.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use XX OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033018